IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Ream et al.
Appl. No.:	09/286,818
Conf. No.:	5472
Filed:	April 6, 1999
Title:	PHARMACEUTICAL CHEWING GUM FORMULATIONS
Art Unit:	1615
Examiner:	Hawes, P.A.
Docket No.:	112703-035

AFFIDAVIT UNDER 37 C.F.R. § 1.132

Sir:

I, Ronald Ream, hereby state as follows:

1. My experience and qualifications are as follows:
   - B.S. in Chemistry from Northern Illinois University – 1964
   - M.B.A. from Loyola University in Chicago – 1970
   - Advanced Certificate in Food Science from Illinois Institute of Technology – 1974
   - 40 years of work experience with 30 years related to foods/drugs

2. I am one of the named inventors of the above-identified patent application and am therefore familiar with the inventions disclosed therein.

3. I have reviewed the outstanding Office Action dated January 11, 2006 pending against the above-identified patent application. As one having ordinary skill in the art, I believe that the scope of the presently pending independent Claims 1, 7 and 19 is clearly understood by the skilled artisan in view of the specification and the examples.

4. The claimed invention of the above-identified patent application relates to a method for delivering a medicament to an individual. The method comprises, in part, providing a chewing gum having at least one medicament. The medicament has a uniform distribution

throughout the chewing gum that is less than a typical amount of medicament that is swallowed by the individual to achieve a bioequivalent effect. The gum is chewed to cause the medicament to be released from the chewing gum composition into the buccal cavity of the individual. The continued chewing of the gum thereby creates a fluid pressure causing the medicament to enter the systemic system of the individual through an oral mucosa of the individual.

5. Applicants have surprisingly found that less medicament or agent can be placed in the chewing gum than is typically orally administered and swallowed by an individual to achieve the same bioequivalent effect due to the absorption of the medicament through the oral mucosa. In fact, Applicants have surprisingly found that in certain instances, for at least certain drugs and agents, the administration of the medicament or agent using chewing gum through the buccal cavity can provide an increased effect even as compared to parenteral administration.

6. The specification provides explicit guidance for assisting one having ordinary skill in the art to determine the scope the present claims. For example, the specification teaches the enhanced absorption of medicaments through the oral mucosa by using chewing gum. Oral administration of drugs is by far the most common method. When administered orally, the drugs are typically ingested or swallowed, and drug absorption usually occurs due to the transport of cells across the membranes of the epithelial cells within the gastrointestinal tract. A further issue effecting the absorption of orally administered drugs is the form of the drug.

7. One having ordinary skill in the art would understand that most orally administered drugs or medicaments are given in the form of tablets or capsules. The tablets or capsules contain a pre-determined concentration of medicament depending on the specific objectives of the medicament and the recipient of the medicament. The pre-determined amount is generally an approved FDA amount of a medicament or a standard amount commonly used in the relevant pharmaceutical or food industry. The standard amount of medicaments in capsules or tablets can also be identified by one having skill by reading the ingredient listing on a package insert or by testing using various analytical techniques such as chromatography. As a result, the

amount of medicament typically administered to achieve a desired effect or to treat a particular disorder is known or is readily ascertainable by those skilled in the art.

8. The experiments set forth in the specification provide further guidance for achieving a bioequivalent effect using a lesser amount of a medicament in a chewing gum versus the typical or standard amount of the same medicament in a tablet. For example, the caffeine study of Experiment 2 demonstrates that the administration of the medicament or agent via a chewing gum through the buccal cavity can provide an increased effect than when the same medicament or agent is swallowed in tablet form. The study compares the bioequivalent effect/bioavailability of caffeine in consumers' bloodstream after chewing caffeine containing gum versus swallowing caffeine pills. These examples demonstrate that less caffeine can be provided in the claimed product than that that is typically ingested, for example, through No Doze, and still achieve as good if not greater effect on a consumer. Experiment 4 demonstrates that the chewing gum agents are indeed adsorbed in the oral cavity.

9. For all the foregoing reasons, as one having ordinary skill in the art, I believe that Applicants' specification and the experimental examples allow the skilled artisan to determine the metes and bounds of the presently pending claims.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001, Title 18, United States Code, and that willful false statements may jeopardize the validity of this patent and any patent issuing therefrom.

Date: 3/2/06

Name: Ronald Ream